

### **REMARKS/ARGUMENTS**

Applicants appreciate the Examiner's thorough examination of the application and request reconsideration of the application in view of the above amendment and the following remarks.

Applicants' remarks with respect to the Examiner's rejections are believed to be sufficient to overcome these rejections; therefore, Applicants' silence as to assertions by the Examiner in the Office Action or certain requirements that may be applicable to such rejections (e.g., whether a reference constitutes prior art, motivation to combine references, assertions as to dependent claims, etc.) is not a concession by Applicants that such assertions are accurate or such requirements have been met, and Applicants reserve the right to analyze and dispute such assertions/requirements in the future. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

### **Status of the Claims**

Claims 1-4, 19-22 and 37-40 have been amended, claims 55-56 have been added and no claims have been cancelled. Therefore, claims 1-4, 9-22, 27-40 and 45-56 are now pending in the application. It is respectfully submitted that no new matter has been introduced by these amendments, as support therefor is found throughout the specification, claims and drawings as originally filed. In view of the above amendments and the following remarks, Applicants submit that all of the pending claims are allowable and respectfully request reconsideration of the present application.

### **Substance of Interview**

A telephonic interview occurred on May 18, 2010; participants were Examiner Aaron Roane and Marc Vivencio (Applicants' Representative). Participants discussed proposed claim amendments focusing around how the catheter body is maintained in a fixed position relative

to the target site while the heating element (or wounding segment) is simultaneously retracted to install the plug. Further, participants discussed the functionality and nuances of the occlusion device shown in FIG. 5 of the present application with an eye towards future amendments. No agreement was reached with respect to the allowability of the pending claims over the cited art of record.

**Rejections –35 U.S.C. § 103(a)**

Claims 1-4, 9, 10, 13, 17, 19-22, 27, 28, 31, 35, 37- 40, 45, 46 and 53 stand rejected as being unpatentable over Vancaillie et al. (U.S. Pat. No. 5,095,917; “Vancaillie”) in view of Tay et al. (U.S. Pat. No. 5,810,810; “Tay”) and further in view of Zeluff (U.S. Pat. No. 4,606,336; “Zeluff”); claims 11, 12, 15, 16, 29, 30, 33, 34, 47, 48, 51 and 52 stand rejected as being unpatentable over Vancaillie in view of Tay and further in view of Zeluff and Barbacci (U.S. Pat. No. 5,531,741; “Barbacci”); and claims 14, 18, 32, 36, 50 and 54 stand rejected as being unpatentable over Vancaillie in view of Tay and further in view of Zeluff and Brundin (U.S. Pat. No. 4,509,504; “Brundin”). The Examiner’s grounds for rejection are hereinafter traversed for at least the following reasons and reconsideration is respectfully requested.

In order to support a rejection under 35 U.S.C. § 103(a), the rejected claims must be obvious in light of the cited references. Furthermore, “[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Regarding claim 1, Applicants respectfully submit that none of the cited references, alone or in any permissible combination, teach, disclose or otherwise suggest a “method of occluding the ovarian pathway of a female body comprising the steps of: providing a device comprising a catheter body defining a proximal end and a distal end, a wounding segment extending distally from the distal end of the catheter body and movable relative to the catheter body between an extended position and a retracted position, a heating element disposed on or about the wounding segment, and at least one plug housed within the wounding segment and sized and dimensioned to be implanted into a target segment within the ovarian pathway; inserting the catheter body and

wounding segment into the ovarian pathway; applying the heating element to a target segment of the pathway, and operating the heating element to heat the target segment; and maintaining both the catheter body and at the least one plug stationary relative to the target segment while simultaneously (i) moving the wounding segment relative to the catheter body from the extended position toward the retracted and (ii) exposing and implanting said stationary plug within the target segment of the pathway.”

To the contrary, Vancaillie specifically teaches an instrument having a hollow tube or catheter body 30 containing two or three plugs 32 and a piston 34 slidably disposed therein. During the procedure, “the piston 34 of the instrument is activated and the instrument [is] simultaneously slightly withdrawn...result[ing] in the release of one plug 32... at the exact level of the destroyed mucosa of the uterotubal junction” (Col. 3, lines 15-19; emphasis added). Hence, one must activate the piston 34 to move and eject the plug while simultaneously withdrawing the instrument (i.e. hollow tube catheter body 30) to ensure that the plug 32 is accurately implanted at the desired location. Accordingly, the user cannot solely rely on the instrument to implant the plug 32 at the precise location because the user must physically withdraw the catheter body 30 relative to the target location to counteract the forward motion of the plug 32 caused by the driving piston 34. Such a procedure invites error because the person performing the procedure could miss the target location, for example, by erroneously commencing withdrawal of the catheter body 30 before actuating the piston to eject a plug 32 and/or eject a plug 32 before commencing withdrawal of the catheter body 30. Further, if the user fails to withdraw the catheter body altogether (or not enough), the plug will miss the target location distally, and if the user over-withdraws the catheter body, the plug will miss the target location proximally. In other words, precise timing and control are required to ensure that the plug is implanted at the precise desired location, which is an imperative requirement to ensure effective tubal occlusion.

The present invention overcomes the above disadvantages and reduces error by eliminating the need to withdraw (or move) the catheter body during the procedure; that is, the user simply allows the device to do the work and is not required to manipulate the catheter during implantation. Both the catheter body and plug remain in a stationary position relative to the target location during implantation while the wounding segment is retracted (relative to the

catheter body) to expose the stationary plug, ensuring that the plug is disposed at the precise desired location. Accordingly, Applicants respectfully submit that Vancaillie fails to teach the method of claim 1, and in fact teaches away from said method by requiring movement of both the catheter body and plug during implantation.

Applicants further submit that none of the other cited references overcome the deficiencies in Vancaillie in meeting the terms of the claimed invention. Tay, at most, teaches an apparatus for sealing vascular punctures without any consideration of retracting the electrodes 50 to facilitate simultaneous installation of a plug for occluding an ovarian pathway for female sterilization. Zeluff, at most, teaches the installation of an occlusion device 10 by extending a separate carrier control device 32 through a hysteroscope 28, and then actuating levers 36 to linearly displace a shaft 37 proximally (i.e. the shaft is not retracted) to, in turn, forwardly eject the occlusion device (see, for example, col. 5, lines 12-52). Further, Zeluff is silent with respect to applying an RF electrode array to a target segment of the ovarian pathway. Brundin, at most, teaches using a hysteroscope to locate the oviduct opening into the uterus and then implanting a water-swallowable article 2 therein; Brundin provides no disclosure or enablement regarding how the article is delivered and implanted. Lastly, Barbacci, at most, teaches a radial light emitting ureteral stent without any contemplation or discussion of a method of occluding an ovarian pathway, much less the currently claimed method.

Therefore, for at least the reasons advanced above, Applicants respectfully submit that independent claim 1 defines patentably over the prior art of record. Reconsideration and withdrawal of the rejection of claims 1 are respectfully requested. Independent claims 19 and 37 recite similar patentable subject matter with respect to claim 1 and, therefore, Applicants respectfully submit that claims 19 and 37 define patentably over the prior art of record for at least the same reasons given in support of the patentability of claim 1. Accordingly, reconsideration and withdrawal of the rejections of claims 19 and 37 are respectfully requested.

Because claims 2-4, 9-18, 20-22, 27-36, 38-40 and 45-54 depend either directly or indirectly from one of claims 1, 19 and 37, Applicants respectfully submit that claims 2-4, 9-18, 20-22, 27-36, 38-40 and 45-54 define patentably over the prior art of record for at least the same reasons set

forth above in support of the patentability of claims 1, 19 and 37 and for reciting additional patentable subject matter. Reconsideration and withdrawal of the rejections of claims 2-4, 9-18, 20-22, 27-36, 38-40 and 45-54 are respectfully requested.

New claims 55-56 depend from and include all of the limitations of claim 1. Accordingly, Applicants assert that said claims define patentably over the prior art of record for at least the same reasons given above in support of the patentability of claim 1 and for reciting additional patentable subject matter. Allowance of claims 55-56 is respectfully requested.

### **Conclusion**

In light of the above Remarks, Applicants respectfully submit that the pending claims define patentably over the cited art of record. All issues raised by the Examiner having been addressed, an early action to that effect is earnestly solicited. If the Examiner believes that a telephone conference with Applicant's attorney would be advantageous to the disposition of this case, the Examiner is cordially requested to telephone the undersigned.

Applicants believe that no fees are due in addition to the RCE fee submitted herewith. However, in the event of a fee deficiency, authorization is hereby given to charge any required fee(s) to Deposit Account No. 50-2855. If an extension of time is deemed required with this submission, please consider this a request for said extension and authorization to charge the corresponding extension fee to Deposit Account No. 50-2855.

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Respectfully submitted,

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